

# **Exhibit B**

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2  
3 IN RE: :SUPERIOR COURT OF  
PELVIC MESH/GYNECARE :NEW JERSEY  
4 LITIGATION :LAW DIVISION -  
:ATLANTIC COUNTY  
5 :  
:MASTER CASE 6341-10  
6 :  
:CASE NO. 291 CT

7  
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8 CONFIDENTIALITY  
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9  
September 12, 2012  
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11  
12 Volume I of the transcript of the  
13 Deposition of CHARLOTTE OWENS, M.D., called for  
14 Videotaped Examination in the above-captioned  
15 matter, said deposition taken pursuant to  
16 Superior Court Rules of Practice and Procedure,  
17 by and before JoRita B. Meyer, a Certified  
18 Realtime Reporter, Registered Merit Reporter,  
19 and Certified Court Reporter for the State of  
20 Georgia, at the offices of Troutman Sanders,  
21 600 Peachtree Street Northeast, Atlanta,  
22 Georgia, commencing at 9:39 a.m.

23 - - -  
24 GOLKOW TECHNOLOGIES, INC.  
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25 deps@golkow.com

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1           decide if they want to learn more about  
2           the system, and ultimately will use  
3           their training, education, and  
4           experience, plus this document, to  
5           decide if they want to use it.

6       BY MR. SLATER:

7           Q.    Did you understand that it was  
8           necessary to clearly and unambiguously  
9           communicate all necessary contraindications,  
10          warnings and precautions, and adverse reactions  
11          to physicians through the IFU?

12          A.    I understand the document should be  
13          clear and unambiguous, yes.

14          Q.    Did you understand that it was  
15          necessary for Gynecare, to the extent that a  
16          risk was understood to exist with the PROLIFT,  
17          to communicate it in the IFU as opposed to  
18          assuming that surgeons would figure out that  
19          risk on their own?

20          A.    I don't think you're giving surgeons  
21          enough credit. Surgeons don't have to figure  
22          out the complications of an area that they  
23          operate. Surgeons are trained to know the  
24          complications of the area in which they  
25          operate.

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1 BY MR. SLATER:

2 Q. Does it mean too much tension?

3 A. It's not that simple.

4 Q. How would a surgeon doing the  
5 procedure be able to objectively verify, based  
6 on an objective standard, that they had placed  
7 or not placed the mesh with excessive tension?

8 A. They would be able to look at the  
9 repair after surgery and see if it looks  
10 relaxed or see if it looks like it's under  
11 tension.

12 Q. So that's how they would do it?

13 A. That's generally how it was done.

14 Q. Did you ever perform the PROLIFT  
15 procedure?

16 A. On the cadavers, yes. In live  
17 people, because I was not practicing during my  
18 tenure at Ethicon, no.

19 Q. Did you ever on your own, without any  
20 other surgeon performing the procedure -- did  
21 you ever place Gynemesh in a human's body?

22 A. No.

23 Q. Look at the adverse reactions,  
24 please. It was your understanding that you  
25 needed to list each of the adverse reactions

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1       that were known to you in Medical Affairs in  
2       this section, correct?

3           A.     Yes.

4           Q.     And you understood that if you failed  
5       to list adverse reactions that you were aware  
6       of, that that would render that warning  
7       deficient to some extent, correct?

8           A.     Deficient?

9           MR. BROWN:  Objection.

10          THE WITNESS:  I would say that we  
11       listed the adverse reactions that we  
12       knew were adequate and sufficient for  
13       this document.

14       BY MR. SLATER:

15          Q.     Well, you just said a moment ago you  
16       agreed with me that you understood you were  
17       supposed to list each of the adverse reactions  
18       that you in Medical Affairs knew existed at the  
19       time of launch, correct?

20          A.     We listed the adverse events that we  
21       knew to be directly related to the information  
22       that we had at this time.

23          Q.     Okay.  Were there risks -- well,  
24       rephrase.

25                 You see where it says, at the end of